ARC 8909B

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 124.301 and 147.76, the Board of Pharmacy hereby amends Chapter 7, "Hospital Pharmacy Practice," Iowa Administrative Code.

The amendments establish criteria for the administration and dispensing of prescription drugs through hospital outpatient services and a hospital emergency department. The amendments define terms specifically related to these hospital outpatient services and the hospital emergency department; address accountability controls for drugs maintained, administered, or dispensed through these services; and specifically address the use of an InstyMeds dispensing system in a hospital emergency department.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the December 30, 2009, Iowa Administrative Bulletin as **ARC 8413B**. The Board received written comments regarding the proposed amendments from three pharmacists. The adopted amendments differ from those published under Notice. In response to comments, the Board amended use of the term "prescription" when referring to the authorization for administration of a drug in the outpatient and emergency departments to alternately include an "order" for administration of a drug in those settings. Paragraph 7.11(2)"c" is changed to eliminate the requirement that all outpatient medication orders be in written format and to specifically address the unique requirements of outpatient medication orders for Schedule II controlled substances, Schedules III, IV, and V controlled substances, and noncontrolled substances. Subrule 7.12(3) is amended to clarify the applicability of the rule when 24-hour outpatient pharmacy services are not available.

The amendments were approved during the April 29, 2010, meeting of the Board of Pharmacy.

These amendments will become effective on August 4, 2010.

These amendments are intended to implement Iowa Code sections 124.301, 124.306, 126.10, 126.11, 155A.13, 155A.27, and 155A.28.

The following amendments are adopted.

ITEM 1. Adopt the following **new** rule 657—7.11(124,126,155A):

657—7.11(124,126,155A) Outpatient services. No prescription drugs shall be dispensed to patients in a hospital outpatient setting. If a need is established for the dispensing of a prescription drug to an outpatient, a prescription drug order shall be provided to the patient to be filled at a pharmacy of the patient's choice.

7.11(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Emergency department patient" means an individual who is examined and evaluated in the emergency department.

"Outpatient" means an individual examined and evaluated by a prescriber who determined the individual's need for the administration of a drug or device, which individual presents to the hospital outpatient setting with a prescription or order for administration of a drug or device. "Outpatient" does not include an emergency department patient.

"Outpatient medication order" means a written order from a prescriber or an oral or electronic order from a prescriber or the prescriber's authorized agent for administration of a drug or device. An outpatient medication order may authorize continued or periodic administration of a drug or device for a period of time and frequency determined by the prescriber or by hospital policy, not to exceed legal limits for the refilling of a prescription drug order.

7.11(2) *Administration in the outpatient setting.* Drugs shall be administered only to outpatients who have been examined and evaluated by a prescriber who determined the patient's need for the drug therapy ordered.

a. Accountability. A system of drug control and accountability shall be developed and supervised by the pharmacist in charge and the facility's outpatient services committee, or a similar group or person

responsible for policy in the outpatient setting. The system shall ensure accountability of drugs incidental to outpatient nonemergency therapy or treatment. Drugs shall be administered only in accordance with the system.

b. Controlled substances. Controlled substances maintained in the outpatient setting are kept for use by or at the direction of prescribers for the nonemergency therapy or treatment of outpatients. In order to receive a controlled substance, a patient shall be examined in the outpatient setting or in an alternate practice setting or office by a prescriber who shall determine the patient's need for the drug. If the patient is examined in a setting outside the outpatient setting, the prescriber shall provide the patient with a written prescription or order to be presented at the hospital outpatient setting.

c. Outpatient medication orders. A prescriber may authorize, by outpatient medication order, the periodic administration of a drug to an outpatient.

(1) Schedule II controlled substance. An outpatient medication order for administration of a Schedule II controlled substance shall be written and, except as provided in rule 657—10.25(124) regarding the issuance of multiple Schedule II prescriptions, shall authorize a single administration of the prescribed substance.

(2) Schedule III, IV, or V controlled substance. An outpatient medication order for administration of a Schedule III, IV, or V controlled substance shall be written and may be authorized for a period not to exceed six months from the date ordered.

(3) Noncontrolled substance. An outpatient medication order for administration of a noncontrolled prescription drug may be authorized for a period not to exceed 18 months from the date ordered.

ITEM 2. Rescind rule 657—7.12(124,126,155A) and adopt the following **new** rule in lieu thereof:

657—7.12(124,126,155A) Drugs in the emergency department. Drugs maintained in the emergency department are kept for use by or at the direction of prescribers in the emergency department. Drugs shall be administered or dispensed only to emergency department patients. For the purposes of this rule, "emergency department patient" means an individual who is examined and evaluated in the emergency department.

7.12(1) *Accountability.* A system of drug control and accountability shall be developed and supervised by the pharmacist in charge and the facility's emergency department committee, or a similar group or person responsible for policy in the emergency department. The system shall identify drugs of the nature and type to meet the immediate needs of emergency department patients. Drugs shall be administered or dispensed only in accordance with the system.

7.12(2) *Controlled substances.* Controlled substances maintained in the emergency department are kept for use by or at the direction of prescribers in the emergency department.

a. In order to receive a controlled substance, a patient shall be examined in the emergency department by a prescriber who shall determine the need for the drug. It is not permissible under state and federal regulations for a prescriber to see a patient outside the emergency department setting, or talk to the patient on the telephone, and then proceed to call the emergency department and order the administration of a stocked controlled substance upon the patient's arrival at the emergency department except as provided in paragraph 7.12(2)*"c"* or *"d."*

b. A prescriber may authorize, without again examining the patient, the administration of additional doses of a previously authorized drug to a patient presenting to the emergency department within 24 hours of the patient's examination and treatment in the emergency department.

c. In an emergency situation when a health care practitioner authorized to prescribe controlled substances is not available on site, and regardless of the provisions of paragraph 7.12(2)*"a,"* the emergency department nurse may examine the patient in the emergency department and contact the on-call prescriber. The on-call prescriber may then authorize the nurse to administer a controlled substance to the patient pending the arrival of the prescriber at the emergency department. As soon as possible, the prescriber shall examine the patient in the emergency department and determine the patient's further treatment needs.

d. In an emergency situation when a health care practitioner authorized to prescribe controlled substances examines a patient in the prescriber's office and determines a need for the administration of

a controlled substance, and regardless of the provisions of paragraph 7.12(2)*"a,"* the prescriber may direct the patient to present to the emergency department, with a valid written prescription or order for the administration of the controlled substance. As soon as possible, the prescriber shall examine the patient in the emergency department and determine the patient's further treatment needs.

7.12(3) *Drug dispensing.* In those facilities with 24-hour pharmacy services, only a pharmacist or prescriber may dispense any drugs to an emergency department patient. In those facilities located in an area of the state where 24-hour outpatient or 24-hour on-call pharmacy services are not available within 15 miles of the hospital, and which facilities are without 24-hour outpatient pharmacy services, the provisions of this rule shall apply.

a. Pharmacist in charge responsibility. The pharmacist in charge is responsible for maintaining accurate records of dispensing of drugs from the emergency department and for ensuring the accuracy of prepackaged drugs and the complete and accurate labeling of prepackaged drugs pursuant to this paragraph.

(1) Prepackaging. Except as provided in subrule 7.12(4), drugs dispensed to an emergency department patient in greater than a 24-hour supply may be dispensed only in prepackaged quantities not to exceed a 72-hour supply or the minimum prepackaged quantity in suitable containers, except that a seven-day supply of doxycycline provided through the department of public health pursuant to the crime victim compensation program of the Iowa department of justice may be dispensed for the treatment of a victim of sexual assault. Prepackaged drugs shall be prepared pursuant to the requirements of rule 657—22.3(126).

(2) Labeling. Drugs dispensed pursuant to this paragraph shall be appropriately labeled as required in paragraph 7.12(3)*"b,"* including necessary auxiliary labels.

b. Prescriber responsibility. Except as provided in subrule 7.12(4), a prescriber who authorizes dispensing of a prescription drug to an emergency department patient is responsible for the accuracy of the dispensed drug and for the accurate completion of label information pursuant to this paragraph.

(1) Labeling. Except as provided in subrule 7.12(4), at the time of delivery of the drug the prescriber shall appropriately complete the label such that the dispensing container bears a label with at least the following information:

1. Name and address of the hospital;
2. Date dispensed;
3. Name of prescriber;
4. Name of patient;
5. Directions for use;
6. Name and strength of drug.

(2) Delivery of drug to patient. Except as provided in subrule 7.12(4), the prescriber, or a licensed nurse under the supervision of the prescriber, shall give the appropriately labeled, prepackaged drug to the patient or patient's caregiver. The prescriber, or a licensed nurse under the supervision of the prescriber, shall explain the correct use of the drug and shall explain to the patient that the dispensing is for an emergency or starter supply of the drug. If additional quantities of the drug are required to complete the needed course of treatment, the prescriber shall provide the patient with a prescription for the additional quantities.

7.12(4) *Use of InstyMeds dispensing system.* A hospital located in an area of the state where 24-hour outpatient pharmacy services are not available within 15 miles of the hospital may implement the InstyMeds dispensing system in the hospital emergency department only as provided by this subrule.

a. Persons with access to the dispensing machine for the purposes of stocking, inventory, and monitoring shall be limited to pharmacists, pharmacy technicians, and pharmacist-interns.

b. The InstyMeds dispensing system shall be used only in the hospital emergency department for the benefit of patients examined or treated in the emergency department.

c. The dispensing machine shall be located in a secure and professionally appropriate environment.

d. The stock of drugs maintained and dispensed utilizing the InstyMeds dispensing system shall be limited to acute care drugs provided in appropriate quantities for a 72-hour supply or the minimum

commercially available package size, except that antimicrobials may be dispensed in a quantity to provide the full course of therapy.

e. Drugs dispensed utilizing the InstyMeds dispensing system shall be appropriately labeled as provided in 657—subrule 6.10(1), paragraphs *"a"* through *"g."*

f. Prior to authorizing the dispensing of a drug utilizing the InstyMeds dispensing system, the prescriber shall offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice.

g. When appropriate for an acute condition, the prescriber shall provide to the patient or the patient's caregiver a prescription for the remainder of drug therapy beyond the supply available utilizing the InstyMeds dispensing system. During consultation with the patient or the patient's caregiver, the prescriber shall clearly explain the appropriate use of the drug supplied, the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice, and the need to complete the full course of drug therapy.

h. The pharmacy shall, in conjunction with the hospital emergency department, implement policies and procedures to ensure that a patient utilizing the InstyMeds dispensing system has been positively identified.

i. The hospital pharmacist shall review the printout of drugs provided utilizing the InstyMeds dispensing system within 24 hours unless the pharmacy is closed, in which case the printout shall be reviewed during the first day the pharmacy is open following the provision of the drugs. The purpose of the review is to identify any dispensing errors, to determine dosage appropriateness, and to complete a retrospective drug use review of any antimicrobials dispensed in a quantity greater than a 72-hour supply. Any discrepancies found shall be addressed by the pharmacy's continuous quality improvement program.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/30/10.